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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|--------------------------------|------------------|
| 10/501,173 | 07/09/2004 | Henryk Struszczyk | 7008USO1 | 6041 |
| 23492 7590 03/01/2007 ROBERT DEBERARDINE ABBOTT LABORATORIES 100 ABBOTT PARK ROAD DEPT. 377/AP6A ABBOTT PARK, IL 60064-6008 | | | EXAMINER WHITE, EVERETT NMN | |
| | | | ART UNIT 1623 | PAPER NUMBER |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 03/01/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/501,173

Applicant(s)

STRUSZCZYK ET AL.

Examiner

Everett White

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed December 20, 2006 has been received, entered and carefully considered. The amendment affects the instant application accordingly:
 - (A) Comments regarding Office Action have been provided drawn to:
 - (I) 103(a) rejections, which have been maintained for the reasons or record.
2. Claims 1-42 are pending in the case.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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4. Claims 1-9 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Goosen et al (US Patent No. 4,942,129) in view of Struszczyk et al (US Patent No. 5,554,445) for the reasons disclosed on pages 2-4 of the Office Action filed September 20, 2006.

5. Applicant's arguments filed December 20, 2006 have been fully considered but they are not persuasive. Applicants argue against the rejection on the ground that the references do not disclose a chitosan-calcium (II) complex wherein the calcium (II) ion content is greater than or equal to 0.1 wt.% relative to chitosan. This argument is not persuasive because the Goosen et al patent does disclose penetration of chitosan into a calcium alginate gel matrix, which forms a chitosan-calcium containing complex. Although, the Goosen et al patent is silent regarding the concentration of the calcium ion in the chitosan-calcium containing complex thereof, the utility of the chitosan complex in the Goosen et al patent as microcapsules falls within the cited utility of the chitosan-calcium complex disclosed in the instant application as having application in medicine and pharmacy, which suggests comparable concentrations of calcium in the Goosen et al patent. Proportions of ingredients, to impart patentability to an otherwise obvious chemical composition, must produce more than a mere difference in degree in the properties of the composition. *In re Fields* (CCPA 1962) 304 F2d 691, 134 USPQ 242. The proportions must be critical, i.e., they must produce a difference in kind rather than degree. *In re Touvay et al.* (CCPA 1958) 264 F2d 901, 121 USPQ 265; *In re Selmi et al.* (CCPA 1946) 156 F2d 96, 70 USPQ 197; *In re Waite* (CCPA 1948) 168 F2d 104, 77 USPQ 586.

Applicants also argue that one of skill in the art would have no motivation to combine or to modify the cited references to arrive at the claimed invention because the references deal with different chitosan compositions. This argument is not persuasive because one of ordinary skill in this art would be motivated to combine the teachings of Goosen et al patent with that of the Struszczyk et al patent since both patents disclose chitosan products used in the preparation of membranes. The Struszczyk et al patent is only cited to show that the polydispersity, deacetylation degree and water retention values disclosed for chitosan in the instant claims are well known in the art.

Accordingly, the rejection of Claims 1-9 under 35 U.S.C. 103(a) as being unpatentable over the Goosen et al patent in view of the Struszczyk et al patent is maintained for the reasons of record.

6. Claims 10-42 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Nies et al (EP 650999 A1) in view of Hashimoto et al (U.S. Patent No. 5,474,989) for the reasons disclosed on pages 4 and 5 of the Office Action filed September 20, 2006.

7. Applicant's arguments filed December 20, 2006 have been fully considered but they are not persuasive. Applicants argue against the rejection on the ground that the Nies et al document fails to disclose steps of adjusting the pH of the solutions thereof to form gels and that the Hashimoto patent fails to disclose chitosan gels of any type. This argument is not persuasive because the Nies et al does disclose adding salt to the chitosan solution thereof, which adjusts the pH of the solution and thus allows gels to be obtained. It is well known in the art that chitosan solutions form gels at pH of about 7. The Hashimoto et al patent is only cited to show that the use of enzymes to degrade chitosan is well known in the art. One of ordinary skill in this art would be motivated to combine the teachings of the Nies et al publication with the teachings of the Hashimoto et al patent since both documents teaches the preparation of drug compositions comprising chitosan. Accordingly, the rejection of Claims 10-42 under 35 U.S.C. 103(a) as being unpatentable over the Nies et al publication in view of the Hashimoto et al patent is maintained for the reasons of record.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Summary

9. All the claims are rejected.


Examiner's Telephone Number, Fax Number, and Other Information

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is 571-272-0660. The examiner can normally be reached on 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-066127. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


E. White


Shaojia A. Jiang
Supervisory Primary Examiner
Technology Center 1600